

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV724615569US  
Express Mail Label Number

July 8, 2005  
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF  
KATOPODIS ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP2003/008436

FILED: 30 JULY 2003

U.S. APPLICATION NO: 10/522,823

35 USC §371 DATE: Not Yet Known

FOR: TOLERANCE INDUCTION WITH HELP OF A COMBINATION OF A  
LFA-1 INHIBITOR AND A COSTIMULATION INHIBITOR AND/OR A  
MTOR INHIBITOR

**MS: Amendment**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is supplemental to the Information Disclosure Statement filed January 31, 2005. Since it is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 of the international application, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-7909

*Thomas R. Savitsky*

Thomas R. Savitsky  
Attorney for Applicants  
Reg. No. 31,661

Date: *July 8, 2005*

FORM PTO-1449  
(REV. 7-85)U.S. DEPARTMENT OF COMMERCE  
PATENT & TRADEMARK OFFICE  
INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO.  
TX/4-325  
APPLICA~~RE~~ NO.  
10/522,823  
APPLICANT  
KATOPODIS ET AL.  
FILING DATE  
Not Yet Known

Group

## U.S. PATENT DOCUMENTS

| EXAMINER INITIAL |    | DOCUMENT NUMBER | DATE     | NAME         | CLASS | SUBCLASS | FILING DATE |
|------------------|----|-----------------|----------|--------------|-------|----------|-------------|
|                  | AA | 2001/0055593    | 12/27/01 | Sypek et al. | 424   | 144.1    | 3/13/01     |
|                  | AB |                 |          |              |       |          |             |
|                  | AC |                 |          |              |       |          |             |
|                  | AD |                 |          |              |       |          |             |
|                  | AE |                 |          |              |       |          |             |
|                  | AF |                 |          |              |       |          |             |
|                  | AG |                 |          |              |       |          |             |
|                  | AH |                 |          |              |       |          |             |
|                  | AI |                 |          |              |       |          |             |
|                  | AJ |                 |          |              |       |          |             |
|                  | AK |                 |          |              |       |          |             |
|                  | AL |                 |          |              |       |          |             |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE    | OFFICE | CLASS | SUBCLASS | TRANSLATION<br>YES       | TRANSLATION<br>NO        |
|--|----|-----------------|---------|--------|-------|----------|--------------------------|--------------------------|
|  | AM | 01/15733        | 3/8/01  | WO     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AN | 02/14865        | 2/21/02 | WO     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AO |                 |         |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AP |                 |         |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AQ |                 |         |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|    |   |
|----|---|
| AR | Förster et al., "Contribution of CD40-CD154-Mediated Costimulation to an Alloresponse in Vivo", Transplantation, Vol. 67, No. 9, pp. 1284-1287 (1999).                            |
| AS | Holländer et al., "On Costimulatory Signals and T Cell Tolerance: Relevance for Transplantation Immunity", Transplantation Proceedings, Vol. 31, Suppl. 1/2A, pp. 25S-32S (1999). |
| AT | Kamoun, "Cellular and Molecular Parameters in Human Renal Allograft Rejection", Clinical Biochemistry, Vol. 34, pp. 29-34 (2001).   |

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449  
(REV. 7-85)U.S. DEPARTMENT OF COMMERCE  
PATENT & TRADEMARK OFFICE

## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO.  
TX/4-3256  
APPLICANT NO.  
10/522,823  
APPLICANT  
KATOPODIS ET AL.  
FILING DATE  
Not Yet Known

Group

EXAMINER  
INITIAL

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|  |    |   |
|--|----|---|
|  | DA | Larsson et al., "Simultaneous Inhibition of B7 and LFA-1 Signaling Prevents Rejection of Discordant Neural Xenografts in Mice Lacking CD40L", Xenotransplantation, Vol. 9, pp. 68-76 (2002).              |
|  | DB | Malm et al., "CTLA41G Induces Long-Term Graft Survival of Allogeneic Skin Grafts and Totally Inhibits T-Cell Proliferation in LFA-1-Deficient Mice", Transplantation, Vol. 73, No. 2, pp. 293-297 (2002). |
|  | DC | Waldmann, "Therapeutic Approaches for Transplantation", Current Opinion in Immunology, Vol. 13, pp. 606-610 (2001).   |
|  | DD | Vincenti, "The Role of Newer Monoclonal Antibodies in Renal Transplantation", Transplantation Proceedings, Vol. 33, pp. 100-1001 (2001).  |
|  | DE | Rayat et al., "Combination of Anti-LFA 1 Antibody with Anti-CD45RB or Anti-CD154 Antibody Promotes Long-Term Porcine Islet Xenograft Survival", Cell Transplantation, Vol. 10, No. 6, pp. 526-527 (2001). |
|  | DF |   |
|  | DG |   |
|  | DH |   |
|  | DI |   |
|  | DJ |   |
|  | DK |   |
|  | DL |   |
|  | DM |   |
|  | DN |   |

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.